2018 Current Fiscal Year Report: Medical Imaging Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Medical Imaging Drugs Advisory Committee	917

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/18/2017	05/18/2019	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 0 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 0

Meetings and Dates

No Meetings

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$0.00	$5,468.00
18a(2). Personnel Pmts to Federal Members	$0.00	$1,094.00
18a(3). Personnel Pmts to Federal Staff	$144,547.00	$142,281.00
18a(4). Personnel Pmts to Non-Member Consultants	$0.00	$3,828.00
18b(1). Travel and Per Diem to Non-Federal Members	$0.00	$0.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$0.00	$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$36,137.00	$35,570.00
18d. Total	$180,684.00	$188,241.00

19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?
The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?
Members are authorities in the fields of nuclear medicine, radiology, epidemiology or statistics, and related specialties. The committee includes one technically qualified voting member who is identified with consumer interests. The Committee may include one non-voting member who is identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?
The committee did not meet during FY-18. It is expected that the committee will meet two to three times during FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?
Members of the committee are drawn from academia, research and/or clinical practice. Their advice and input lends credibility to regulatory decisions made by the agency. The alternate means of obtaining this advice would be to hire large numbers of scientists on a full time basis at great expense to the government.

20e. Why is it necessary to close and/or partially closed committee meetings?
The committee held no closed meetings during FY-18.

21. Remarks
Although this committee did not meet in FY 2018, considerable time was devoted to reappointing current members, maintaining associated records for these activities, and streamlining paper processes within FDA. In addition, time was spent in the routine care and maintenance of the committee: the development of a financial report for this website; updating the roster and number of vacancies on our website; completing the annual ethics report; reviewing financial disclosures of current members and providing ethics training. Since the Committee did not meet, no reporting was required.

Designated Federal Officer

Jennifer A Shepherd DFO

Committee Members	Start	End	Occupation	Member Designation
Applegate, Kimberly	07/30/2015	06/30/2019	Division Chief of Pediatric Radiology, Professor of Radiology and Pediatrics, University of Kentucky	Special Government Employee (SGE) Member
Bolch, Wesley	09/28/2016	06/30/2020	Director, Department of Biomedical Engineering, University of Florida	Special Government Employee (SGE) Member
Dainiak, Nicholas	07/01/2014	06/30/2019	Clinical Professor of Medicine, Yale University School of Medicine	Special Government Employee (SGE) Member
Frank, Richard	03/30/2016	10/31/2019	Chief Medical Officer Siemens Healthcare	Representative Member
Hackney, David	09/28/2016	06/30/2020	Chief of Neuroradiology, Beth Israel Deaconess Medical Center	Special Government Employee (SGE) Member
Hardie, Andrew	09/28/2016	06/30/2020	Associate Professor of Radiology and Urology, Medical College of South Carolina	Special Government Employee (SGE) Member
Herscovitch, Peter	07/30/2015	06/30/2019	Department Director, PET Department, National Institutes of Health Clinical Center	Regular Government Employee (RGE) Member
Jacobs, Paula	09/28/2016	06/30/2020	Associate Director, Division of Cancer Treatment and Diagnosis, NCI, NIH	Regular Government Employee (RGE) Member
Kwong, Raymond	08/28/2017	06/30/2021	Associate Professor of Medicine, Harvard Medical School	Special Government Employee (SGE) Member
Royal, Henry	08/28/2017	06/30/2021	Associate Director; Division of Nuclear Medicine; Mallinckrodt Institute of Radiology	Special Government Employee (SGE) Member
Toledano, Alicia	07/30/2015	06/30/2019	President, Biostatistics Consulting, LLC	Special Government Employee (SGE) Member
Wiegers, Susan	08/28/2017	06/30/2021	Senior Associate Dean Faculty Affairs Senior Associate Dean Graduate Medical Education Professor of Medicine	Special Government Employee (SGE) Member

Number of Committee Members Listed: 12

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Medical Imaging Drugs Advisory Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Medical Imaging Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

4

Number of Recommendations Comments

The committee made 4 recommendations from FY-03 through the FY-18. The committee was re-established in 2011. See question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

50%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

50%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑

Reallocated resources	☐
Issued new regulation	✓
Proposed legislation	☐
Approved grants or other payments	☐
Other	✓

Action Comments

FDA approves or chooses not to approve a new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	☐

Access Comments

NA